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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/402,093	09/29/1999	KAZUHIRO OHSUYE	001560-373	5533

21839 7590 01/13/2005

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EXAMINER

SLOBODYANSKY, ELIZABETH

ART UNIT PAPER NUMBER

1652

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/402,093

Applicant(s)

OHSUYE ET AL.

Examiner

Elizabeth Slobodyansky, PhD

Art Unit

1652

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 03 January 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 03 January 2005. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☒ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

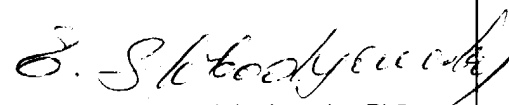
Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 27, 29-40, 45, 47-53.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_



Elizabeth Slobodyansky, PhD  
Primary Examiner  
Art Unit: 1652

Continuation of 2. NOTE: While Applicants replaced the term "unit", the phrase "added thereto" as opposed to "comprise" is unclear because it does not necessarily imply the fusion protein comprising the peptide of interest and a helper peptide connected via a cleavage site and may be construed as "added to" protective peptide, for example. Furthermore, the amendment to the specification does not place the application in a better form, see below.

Continuation of 5. does NOT place the application in condition for allowance because: Applicants argue that "RHHGP[G]" and "RHHGP 1" are "not amino acid sequences, but rather symbols of peptides" (Remarks, page 14). This is not persuasive because whether they are symbols or sequences they have the same sequence identifier (SEQ ID NO:25) assigned to them. Thus, the same sequence of SEQ ID NO:25 represents two different peptides. With regard to the reference SEQ ID NOs: 8 and 25 as comprising a site cleaved by Kex2 protease, Applicants refer to "page 17, lines 9-13 of the specification" (page 15). This is not persuasive because the specification at page 17 teaches that Kex2 protease cleaves the bond after Lys-Arg, Arg-Arg or Pro-Arg. SEQ ID NO:25 does not comprise any of the above pairs of the amino acids. While the site cleaved by Kex2 may comprise SEQ ID NO:8, the sequence of SEQ ID NO:8 does not comprise the site cleaved by Kex2. With regard to the 112, 1<sup>st</sup> paragraph, write description rejection, Applicants argue that "modification to the GLP-1 sequence by skilled artisan to arrive at an appropriate derivative would be standard and is supported by the Specification, such that a GLP-1 derivative would not have an amino acid sequence with an unknown homology to human GLP-1" (page 17). This is not persuasive because while the derivative of a known structure is described and enabled, the derivative is not claimed by the structure. With regard to the enablement rejection, Applicants do not go beyond Arguments presented previously and discussed in the Final Office action mailed July 1, 2004.